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08/888202

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/888,202	07/07/97	PIMENTEL	J

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HM21/0818

EXAMINER

UNCLASS. ART UNIT PAPER NUMBER

1642
1642

DATE MAILED: 08/18/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Election Filed 8/1/98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-4, 8, 11, 14, 17-22 & 25 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4, 8, 14, 11, 17-22 & 25 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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1. The Election filed June 1, 1998 (Paper No. 4) in response to the Office Action of March 30, 1998 (Paper No. 3) is acknowledged and has been entered. Claims 1-4, 8, 11, 14, 17-22 and 25 are pending in the application and are currently under prosecution.
2. It is noted that Applicant's clearly admits on the record that the species of Second Section 10, Section 13 and Section 16 are obvious variants and therefore the election of species requirement in these sections is withdrawn. The election of species in the other sections is made without traverse.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It has not been submitted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."
5. Claims 1-4, 8, 11, 14, 17-22 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 8, 11, 14, 17-22 are indefinite because claims 1 recites the term "decreasing". The term "decreasing" is a relative term and is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 14 is indefinite because it recites the phrase "further processed". The antibody is not in any way processed in claim 1 from which claim 14 depends therefore it is not clear how it can be further processed.

Claim 25 is indefinite because it recites the phrase "said animal", it is not clear which animal is being referred to in the method part of the claim. The rejection can be obviated by amending the claim to clearly define "a first animal" and "a second animal which is the producer animal"

Claim 25 is indefinite in the recitation of the term "derived". The claim is confusing because it is not clear whether the antibody is isolated from the producer animal or produced by.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 25 is rejected under 35 U.S.C. § 102(b) as being anticipated by Murase

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et al (Atherosclerosis, 1981, 39:293-300) as evidenced by .

The claim is drawn to a method of transferring antibodies from an animal to other animals comprising administering to said animal an antibody containing substance derived from a producer animal wherein said producer animal had been immunized with lipase wherein lipase regulates a biochemical process in the gastrointestinal tract.

Murase et al teaches a method of transferring antibodies from a laboratory rabbit immunized with lipase to rats. It was well known in the art at the time the invention was made that lipase regulates biochemical processes in the gastrointestinal tract.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

9. Claims 1- 4, 8, 11, 14 and 17-22 rejected under 35 U.S.C. § 103 as being

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unpatentable over US Patent No. 4,598,089 in view of Moloney (Livestock Production Science, 1995, 42:239-245), Flint (Proceedings of the Nutrition Society, 1992, 51:433-439), Ohkaru et al (Clin. Chim. Acta (1989) 182:295-300) or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895.

The claims are drawn to a method of decreasing fat absorption in mammals by feeding an avian antibody that binds lipase thereby inhibiting its activity in the gastrointestinal tract wherein said antibody is produced against an animal antigen and is produced in avian eggs, obtained from unfractionated whole eggs wherein the antibody is freeze dried, orally fed in a variety of forms, wherein decreased fat absorption is due to a decreased lipase activity whereby fat is extracted and not absorbed in the gastrointestinal tract.

US Patent No. 4,598,089 teach methods for treating or preventing obesity in a mammal by administration of tetrahydrolipstatin which is an inhibitor of pancreatic lipase (see Abstract) and further teach that the digestion of fats (triglycerides) taken in with food is effected in the intestine by pancreatic lipase and by inhibiting pancreatic lipase, food fats are not cleaved and resorption and utilization of these substances is partially prevented and the triglycerides are excreted in unchanged form (col 3, lines 20-30) and further teaches the administration of tetrahydrolipstatin in food to test animals and further demonstrate a great increase in unaltered triglyceride excretion (col 3, lines 58-col 4 line 2) and claim a method of treating obesity in an afflicted mammal comprising administering tetrahydrolipstatin (see claim 9). US Patent No. 4,598,089 teaches as set forth above but does not teach a method of decreasing fat absorption in mammals by feeding an avian antibody that binds lipase thereby inhibiting lipase activity in the gastrointestinal tract wherein

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said antibody was produced in avian eggs, obtained from unfractionated whole eggs wherein the antibody is freeze dried and orally fed in a variety of forms.

Moloney teaches that medical advice to restrict energy intake from total unsaturated fat has heightened consumer interest in fat content of foods and in meat in particular and because steroid hormone use in beef production for decrease of fat deposition has been prohibited, passive immunological methods are being used to decrease fat content of meat and suggests that future developments of this technology require the identification of specific antigenic determinants and their use as antigens and further teach that the use of the antibodies derived from these antigens could lead to commercially important improvements in the efficiency of lean meat production without adverse effects on animal welfare or meat quality (see Abstract).

Flint teaches that deposition of excess energy in the form of triacylglycerol adipose tissue has become an undesirable trait both in animals and man which is a driving force in the effort to reduce fat content in domestic species (p. 433, para 1) and teaches various immunological methods for manipulation of adiposity and suggests that one strategy could involve the immunoneutralization of gastrointestinal substances that have direct lipogenic effects on adipose tissues (p. 434, para 3).

Ohkaru et al teach a monoclonal antibody raised against pancreatic lipase which partially inhibits lipase activity (see abstract).

JP 02140294 specifically teaches a monoclonal antibody against pancreatic lipase which hinders lipase activity (see abstract).

US Patent No. 5, 585,098 teaches oral administration to cattle, in animal feed, of chicken yolk immunoglobulins to inhibit pathogenic organisms. Coleman

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teaches the advantages of egg yolk antibodies, for example, chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G and show great acid and heat resistance, extraction of yolk antibodies can be performed even on a large scale without costly investment and concentrating the antibody from egg yolk is a relatively straightforward process (col 5, lines 35-67). Most antibodies are contained in the yolk and the yolk is usually separated from the collected egg or eggs for use in the production of the desired antibody (col 6, lines 2-22) and further teaches that the antibodies are in the form of a powder and are obtained from the yolk without fractionation (claims 17 and 18).

US Patent No. 5,080,895 teaches the use of antibodies derived from avians in feed substances and teaches that the oral administration of antibodies was desirable in the art (col 3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody of Ohkaru et al or JP 02140294 for the tetrahydrolipstatin of US Patent No. 4,598,089 because both molecules are inhibitors of pancreatic lipase and because Moloney suggests the identification of specific antigenic determinants to be used in immunological methods to decrease fat content in meat and because Flint specifically suggests that one strategy of immunomodulation of adiposity is the immunoneutralization of gastrointestinal substances that have direct lipogenic effects on adipose tissues. Further, it would have been *prima facie* obvious to administer avian antibodies against lipase (produced from animal antigens since the method of US Patent No. 4,598,089 is performed in animals), produced in eggs, in various feed forms because US Patent No. 5,585,098 teaches the successful oral administration of

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chicken yolk immunoglobulins to cattle in feed and US Patent No. 5,080,895 teaches the use of antibodies derived from avians in feed substances. Finally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to freeze dry the antibodies into powder form because lyophilized reagents store well. One of ordinary skill in the art would have been motivated to substitute the antibody of Ohkaru et al or JP 02140294 for the tetrahydrolipstatin of US Patent No. 4,598,089 because both molecules are inhibitors of pancreatic lipase and because Moloney and Flint teach the importance of immunological manipulation of fat deposition and adiposity. One of ordinary skill in the art would have been motivated to administer avian antibodies against lipase because US Patent No. 5,080,895 teaches that oral administration of avian antibodies was desirable in the art. Finally one of ordinary skill in the art would have been motivated to freeze dry the antibodies to a powder form to insure a ready supply of intact, stable antibodies.

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the

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applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

August 12, 1998



LILA FEISEE
SUPERVISORY PATENT EXAMINER